

## **Clarification of Demonstration Solicitation Requirements**

At this time, we do not intend to have a bidders' conference. Questions regarding this demonstration may be e-mailed to the following persons:

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We will respond to questions in writing or by phone, and make the information we provide available to all interested parties in the document you are currently reading, which will be updated weekly based on the questions we receive.

**The following information is based on inquiries we have received through September 22, 2006.**

### **Corrections to the Solicitation**

- We have identified an incorrect url for the “Application for Federal Assistance” Standard Form 424 mentioned on page 23. The correct url for the SF-424, SF-424a and SF-424b, which should be included in your application, is: <http://www.whitehouse.gov/omb/grants/forms.html>
- Applicants are also required to include the “Medicare Waiver Demonstration Application Data Sheet” with their application. This sheet is available for downloading on the demonstration website.

### **Eligible Organizations**

- Eligible organizations do not need to be on the GSA-approved list. This is a full and open competition among organizations with the capability to meet the requirements of the solicitation. Eligible organizations are defined as existing providers of risk reduction services, which may include disease management organizations, and other organizations that have the capacity to meet the requirements of the solicitation.
- Organizations may enter into contractual agreements with other organizations to provide the services required under this demonstration. For example, an organization can contract with a health risk appraisal software developer.
- If an organization enters into contractual agreements with other organizations to provide the services required under this demonstration, CMS will consider the individual experience and expertise of each individual organization if the newly formed organization does not have experience in working together to deliver the required demonstration services.

- While this demonstration has a national and local component, eligible organizations must be able to provide services to beneficiaries regardless of where they live. CMS will randomly assign populations to the organization. For example, an organization located in Baltimore, Maryland, might be assigned zip codes in Oregon, Texas, Michigan, and Vermont.

### **National and Community Resources**

- CMS will not provide organizations/vendors with lists of national and community resources. Eligible organizations would have the capability of identifying appropriate national resources to refer participants to for behavior change support for the national component of this demonstration. CMS will randomly assign two information and referral assistance (I&R/A) programs to each organization/vendor. The organization/vendor will refer participants in the local component of the demonstration to the I&R/A, which will provide referrals to local resources.

### **Study Design**

- CMS designed this study to include 3 arms rather than 2 because there is some evidence to suggest that completing the HRA itself could have a minor, yet negligible, impact on behavior. CMS wanted to be able to capture this impact. CMS also wants to compare the outcomes of standard and enhanced interventions to understand the varying level of impact that more intensive interventions have on behavior change and costs.
- The sample sizes presented in the solicitation are sufficient for detecting statistically significant differences. Please refer to the slide presentation on the demonstration website for a more detailed discussion.

### **Evaluation**

- CMS will have a separate solicitation for the evaluation of this demonstration. While Medstat considered evaluation issues in the design of this demonstration, the evaluation has not yet been designed.
- In addition to cost outcomes, we expect the evaluation will include health and satisfaction outcomes.
- When comparing outcomes of the demonstration, we anticipate that the evaluation will be conducted two ways, including and excluding those who opt-out of the demonstration.
- The \$10 incentive for completion of each of the 4 HRAs is included in our budget neutrality estimates.

### **Payment and Withhold Methodology**

- CMS will pay the selected organizations a per-member-per-month fee for each intervention participant in this demonstration. A participant is a person who completes and returns the HRA. Vendors should consider their experience in recruitment and retention in developing their estimates for this demonstration.

Recruitment costs for the vendor's total assigned population, not just the people who return HRAs, should be factored into the PMPM.

- Please refer to pages 20-23 of the solicitation for more information regarding the payment methodology.
- CMS would accept a proposal that includes a tiered payment structure, i.e., different PMPM rates for each year.
- Organizations will be expected to enter into a subcontractual arrangement with the two local information and referral assistance programs that will be randomly assigned to them and to provide them minimal funding each year of the demonstration (page 8). For budget submission purposes for this application, assume providing \$10,000 a year to each of these organizations for three years.
- Additional funding for community programs will not be provided by CMS under this demonstration.
- The organization's liability under this demonstration is limited to the withhold. CMS will not place any of the organization's other fees at risk.
- CMS may approach organizations whose proposals are viewed favorably by selection panels to bring bids in line with expectations, both in pre- and post-selection phases.
- An internal system will be developed by CMS to process payments to the vendors in this demonstration.

## **Recruitment**

- CMS expects to jointly draft an invitation/recruitment letter with the vendors, which the vendors will mail to their assigned population at the beginning of this demonstration. This letter will include information regarding how to "opt-out" of the demonstration. Beneficiaries who opt-out will be removed from the targeted pool. Beneficiaries who do not opt-out are considered eligible for recruitment into the demonstration and will be sent an HRA each demonstration year during the recruitment and enrollment period, even if they did not complete the HRA the previous year(s).
- When a beneficiary completes an HRA for the first time, the vendor will alert CMS, and CMS will randomize the beneficiary into one of the three study arms.
- The recruitment and enrollment period will be the first three months of each of the three demonstration years. Vendors will be expected to send HRAs to people who may not have completed HRAs the previous year, but who did not opt out of the demonstration. CMS will randomly assign people completing the HRA for the first time, regardless of the demonstration year.
- Vendors will also be expected to administer HRAs to participants who completed an HRA the previous year(s). It will be the vendor's responsibility to retain their participants from year-to-year. It is possible for a person to complete the HRA in year 1, not to complete it in year 2, but to complete it in year 3. If a participant in year 1 does not return the HRA in year 2, the vendor will not be paid the PMPM for that person in year 2. However, if the person completes the HRA in year 3, then the vendor would be paid for that person in year 3, and the person would remain in their originally assigned intervention arm.

- Vendors will be expected to maintain a 40% participation rate each year of the demonstration. CMS is not providing information regarding participation rates of older adults in these types of programs to assist applicants in developing their assumptions. We recommend that applicants review the literature.
- Applicants are expected to include their recruitment costs in their budget.
- CMS will not provide e-mail addresses or phone numbers to vendors to use in recruiting beneficiaries for this demonstration. Beneficiary mailing addresses will be provided.
- Applicants should include the approximately \$10 incentive for completing the HRA in their budget for this demonstration. CMS believes that approximately \$10 is sufficient incentive for completing the HRA each year. The total for the incentive over the course of the demonstration is \$40, given that an HRA is completed at the beginning of each demonstration year and at the end of the final year. Applicants may propose alternative methods for distributing the incentive over the course of the demonstration.

### **Target Population**

- The target population for this demonstration will be beneficiaries who are not enrolled in Medicare Advantage or hospice. We intend to identify people who are living in the community and not living in institutions.
- CMS will identify the target populations and randomly assign them to each vendor.
- Sample sizes for each arm are large enough to detect significant differences in costs. CMS expects applicants to address the sample size in the solicitation.
- CMS will not provide additional information, such as Medicare claims data, to supplement data collected in the HRA.

### **HRA and Intervention Arms**

- CMS expects vendors to have the ability to provide their HRA and program interventions in Spanish.
- Both Arm 1 and Arm 2 will provide tailored, individualized support and counseling to help people reduce risk factors that cause or exacerbate disease or injury. Arm 2 is expected to provide more intensive interventions to participants in that arm, either through additional tailored behavior change modules, more frequent interactions, or greater access to health educators to support risk reduction efforts.
- It is expected that the random assignment of participants to the intervention arms will result in groups with an equal distribution of risk factors. Thus, the participants in Arms 1 and 2 will be similar. Both arms should provide programming for participants at greater risk.
- It is expected that the costs for providing services to participants in arm 2 will be higher than for providing services in arm 1. Vendors should consider averaging these costs across all participants in deriving their PMPM rate.
- It is up to the vendor's discretion to decide whether the interventions provided in Arms 1 and 2 vary significantly or are similar.

## **Evaluation Process and Criteria**

- There have been questions regarding the differences in the language used to describe the requirements for the “Description of Risk Reduction Services” and “Organizational Capabilities,” on pages 18-19 and the evaluation criteria on page 27. Please include information on program participant recruitment and retention in the “Description of Risk Reduction Services” section of your application. Organizations should include information on the evaluation of the effectiveness of their existing program services and outcomes, such as, scientific studies or publications, in the “Organizational Capabilities” section of the application.

## **Available Funding for Each Organization**

- CMS has limited funding and plans to award up to five organizations for this demonstration.

## **Behavior Change Models**

- CMS expects interventions to be based in behavior change theory.
- CMS will give equal consideration to interventions that integrate features of more than one model.
- CMS is not paying for weight loss or exercise programs. CMS is paying for tailored feedback, counseling, and support for behavior change and risk factor reduction. Supporting a person in their efforts to become physically active or lose weight is appropriate; paying for gym memberships and weight loss programs is not.
- Vendors can offer incentives for activities other than HRA completion, and can administer HRAs more frequently. However, participation rates will be based on completion of the HRA during the three-month period at the beginning of each year.

## **Risk Factors to be Addressed in the Demonstration**

- We are looking for organizations with programs that currently address or could be customized to address the risk factors identified in the solicitation. While obesity is one of many risk factors we expect applicants to address, qualified applicants would be able to address all of the risk factors listed in the solicitation.

## **Differences between the Senior Risk Reduction Demonstration (SRRD) and Medicare Health Support (MHS)**

- MHS targets beneficiaries with specific diseases; SRRD does not target by chronic disease.

- MHS focuses on helping beneficiaries manage diseases, which involves healthy behaviors, but also disease-specific types of behaviors. SRRD focuses on supporting beneficiaries in engaging in healthy behaviors, including appropriate use of preventive services and healthy lifestyles, and using available community resources to support them in behavior change.

### **Partnering Relationships**

- Organizations can provide services under the demonstration using direct staff or subcontract to other organizations, or a combination of both. Organizations will be expected to coordinate and oversee all outsourced activities and retain the ultimate responsibility for all demonstration activities under the awards. Additionally, organizations are required to package programs so that all aspects are delivered in a seamless fashion to participants. Organizations must make clear in their proposals the names of these subcontractors and the nature and scope of activities that they will deliver.

### **History of the Senior Risk Reduction Demonstration**

- As part of the CMS Healthy Aging Project, CMS commissioned RAND to produce an evidence report on health risk appraisal programs. RAND recommended that CMS consider a demonstration to test health risk appraisal programs in Medicare. This evidence report is available for downloading on the demonstration website. CMS contracted with Thomson-Medstat for assistance with the design of this demonstration.